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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 885,361	06 20 2001	Birendra K. Patnaik	498-128 CPA CON	4945

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WASHINGTON, DC 20005

EXAMINER
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MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

VC

DATE MAILED: 02 12 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

09/885 361

PATNAIK ET AL

## Office Action Summary

Examiner

Art Unit

Jennifer Kolb Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-7 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 3-7 and 13-30 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

## DETAILED ACTION

### *Supplemental Election/Restrictions*

1. This action is supplemental to the election of species required by Paul Prebily in Papers 5 and 8 (on 10/02 and 11/02, respectively) and the restriction between article and new method claims of December 9, 2002. Due to the election of method claims, the following new restriction is applied and supercedes the election of 12/9/2002:
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 3-7, drawn to a medical device, classified in class 623, subclass 1.43.
  - II. Claims 13-16, drawn to a method of coating the surface of an article by reacting various agents, classified in class 427, subclass 337.
  - III. Claims 17-23, drawn to a method of coating the inner surface of an ePTFE vascular graft by reacting various agents, classified in class 427, subclass 2.25 or 230.
  - IV. Claims 24-26, drawn to a method of coating an article with  $-O=C-NH-$  spacer- $NH-C$ -bioactive agent, classified in class 427, subclass 2.1.
  - V. Claims 27-30, drawn to a method of coating an article with  $-O=C-NH-NH-$  [hydrophilic amine terminated spacer]- $NH-C=O-$ [bioactive agent], classified in class 427, subclass 2.24.

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The inventions are distinct, each from the other because of the following reasons:

3. Inventions II-V and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be use to make other and materially different products such as a coated water pipe. Alternatively, the product as claimed can be made by another and materially different process, such as not pre-treating with plasma.
4. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as for coating the outer surface of an article or coating a medical device other than an ePTFE vascular graft, such as coating a silicone contact lens. See MPEP § 806.05(d).
5. Inventions II and III are unrelated to Inventions IV and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation and different effects. The Inventions of Groups II and III require reaction steps to create a bio-active coating in the presence of dehydrating agents. Groups IV and V make use of already-prepared bio-active coatings that could be made from a variety of reactions.

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The Inventions of Groups IV and V require plasma treating within an ionization chamber, which Inventions II and III do not. The hydrophilic groups of Inventions II and III could be applied through a variety of other methods.

Lastly, the Inventions of Groups II and III require the use of a bioactive agent constructed of: hydrophilic groups-polymer-amine group-spacer-amine group-bioactive agent, which are different from the specific compositions of Groups IV and V, outlined in paragraph 2.

6. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different operation, functions, and effects. The chemical of Group V requires an additional -NH group, an oxygen on the last carbon group, and a hydrophilic amine terminated spacer group. Group IV does not require the extra -NH or =O group and the spacer group of Group IV appears to be oxygenated polyolefin, from the species election of Amendment B, Paper 9, on 12/4/2002.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for each of the Groups is not required for the others, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. During a telephone conversation between Paul Prebilic and Mr. Salehi on 12/9/2002 a provisional election was made with traverse to prosecute the invention of Group II, the method, claims 13-30. During this telephone interview, Mr. Salehi clarified the election made by the December 4, 2002 response. In particular, the moiety listed for the first species set (i.e. RI) has a typographical error in it. During the 12/9 conversation, Mr. Salehi elected the first listed moiety on line 10 of claim 1 (i.e. the carbonyl amine). Also, Mr. Salehi elected antithrombotic agents for the prosecution from Species set 3. Both of these elections were made with traverse. The second species set elected was clearly set forth to be oxygenated polyolefines in the December 4, 2002 response. Affirmation of this election must be made by applicant in replying to this Office action.

Upon transfer of the case to the methods examiner, Jennifer Michener, this new examiner found that a further restriction was required between the various method inventions, as set forth above.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Response to Arguments***

12. Applicant's election with traverse of certain species in Paper No. 9 is acknowledged. The traversal is on the ground(s) that even though the inventions are independent or distinct, that there is no serious burden to search and examine all of the pending claims. The restriction traversal has been considered but it not deemed to be persuasive. The searches for different classes of inventions are different. Therefore, the art used in the prosecution of one class of invention is different than that used for another. Further, different issues will arise during the course of prosecution of different classes of inventions. For all of these reasons, the examination of all groups and all species would be unduly burdensome. Within the species election, different art would be required to examine the different elements of each group. During prosecution,

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issues will arise if the art used to reject one species of the Markush group becomes irrelevant in light of cancellation of that species from the Markush group.

**Conclusion**

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener  
February 9, 2003



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